UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,368	10/26/2001	James P. Hoeffler	IVGN 274.2	2504

52059 7590 10/25/2006

INVITROGEN CORPORATION
29851 WILLOW CREEK ROAD
EUGENE, OR 97402-9132

EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,368	HOEFFLER ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,21-24,48-50,61,64 and 68-87* is/are pending in the application.

4a) Of the above claim(s) *21-24,48-50,61,64,68-70,83 and 85-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,71-82 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18,21-24,48-50,61,64 and 68-87* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' Species Election of Group II – claims 18, 71-82 and 84 with traverse is acknowledged (Response Paper Filed 7/27/06). Applicant does not traverse the Restriction Requirement on the grounds of lack of patentable distinctness. In particular Applicant argues that the antibodies recited in the claims, while patentably distinct, have a commonality of operation, function and effect with respect to the claimed methods and should be examined together. The argument has been carefully considered but not found persuasive for the following reasons:.

This is not found persuasive because MPEP § 808.02 recites:

> Where related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c)- § 806.05(i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof, (B) A separate status in the art when they are classified together, or (C) A different field of search.

In the instant case, (A) -The Restriction Requirement under 35 U.S.C. § 121 in the Species Restriction mailed 6/27/06 established distinctness of the inventions and separate classification thereof (antibodies having recognized binding for different antigens and antibodies with unknown specificity-unknown binding):

(C) With respect to a different field of search – Because these inventions are distinct and have acquired separate status in the art, recognized divergent subject matter, and because the search required for each invention is not substantially coextensive with the search required for the remaining invention, restriction for examination purposes as indicated is proper.

Please note that the classifications in the restriction are illustrative only and do **not** represent all the classes and subclasses, which must be searched for each invention; nor is the search limited to issued US patents, but rather includes published foreign patents and applications as well as literature search.

2. Applicants further argue that only claim 86 does not belong in the elected Group II. This argument was carefully considered but not found persuasive because Group I is drawn to antibodies with unknown specificity and claim 86 specifically recites "antibodies with unknown specificity". Accordingly claim 86 remains in Group I. With respect to the additional claims numbered 21-24, 48-50, 61, 64, 68-70, 83, 85, and 87; applicant argues that the claims do not require the use of *uncharacterized antibodies with unknown specificity*. This argument was carefully considered but not found persuasive because Group II is drawn to antibodies with recognized binding antigens. The additional claims require additional search and consideration with no mention of antibody characterization like independent claim 18. Accordingly, they have been placed in Group I wherein the antibody specificity is unknown or not required to be known like Group II. The species restriction is maintained.

3. Further, the combination of Groups I and II for examination on the merits is deemed incorrect. The merging of these groups would combine patentably distinct species inventions.

The Restriction Requirement is still deemed proper and is therefore made **FINAL.**

4. Currently, claims 18, 21-24, 48-50, 61, 64, and 68-87 are subject to Species Restriction and Election Requirement. Claims 21-24, 48-50, 61, 64, 68-70, 83, and 85-87 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 18, 71-82 and 84 are currently under examination.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 18, 71-82 and 84 are rejected under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "contacted" in claims 71-82 and 84 are vague and indefinite because it is not clear which array is intended to be contacted (step **a** only, step **b** only, or both steps **a** and **b**). Claim 18 recites two contacting steps and the dependent claims merely recite a single contact but makes no distinction with respect to the contacting steps of claim 18. The specification does not provide a standard for ascertaining the requisite contact, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As recited the metes and bounds of the claims cannot be determined. It is suggested that the claims clearly refer to step a or b or both for clarify. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 18 and 71-75 are rejected under 35 U.S.C. 103(a) as being obvious over Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897).

Ekins et al. teach method to detect proteins via multianalyte microspot immunoassys. An array of antibodies (device comprising multiple immobilized agents for protein detection such as antibodies) is exposed to proteins to monitor the expression and properties of a large number of proteins. See abstract and figures 4 and 5.

The detection procedure can be evaluated with a radioactive isotopes (i.e. I^{125}), an enzyme, chemiluminescent label, or fluorescence label. See page 1960. In one embodiment dual microspot assay devices are compared. See page 1961 figure 8 for example. The microarrays taught by Ekins can measure tens, hundreds, or thousands of analytes. Thus the array may comprising 106 Ab (antibody) micro-spots each directed against a different analyte See abstract.

Ekins et al. differ from the instant invention in not specifically teaching the generation of binding patterns for comparison.

However Yates et al. disclose the evaluation of binding patterns to identify peptide amino acid sequences. See abstract. Antibody-protein binding is employed to measure cellular proteins (resting state –normal state). The protein pattern or fragment is stored and compared with database patterns to determine diseases and/or disorders (stimulated state).

Although the references are silent with respect to the cell proteins being evaluated in a cell lysate, absent evidence to the contrary the reference to Yates et al. read on cell lystates because they teach protein digestion of lysing for determination. See column 17 line 61 through colum 18 line 36.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use protein patterning procedures as taught by Yates,III et al. in the high through put protein pattering procedure/microspots of Ekins et al. because Yates, III et al. taught that binding patterns could not only identify disease and or disorders but could further identify the sequence or sub-sequences of the proteins/peptides involved. See column 2 lines 1-19.

II. Claims 76-79 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) and in further view of James F. Cupo (Journal of Chromatography, 569, 1991, 389-40).

Please see Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) as set forth above.

Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) differ from the instant invention in not teaching protein expression pattern evaluation in cancer diseases or virus cell lines (like T cells).

However, Cupo teaches a two-dimensional polyacrylamide gel electrophoresis procedure to measure matrix proteins. The proteins are tissue-type specific and can reflect changes in the state of differentiation of a cell. The method can further distinguish between a diseased cell and a normal cell. The disease states include various cancers, autoimmune disease, and adenoviral infection. See abstract. The method is quick and efficient employing the appropriate antibodies to the protein of interest. Page 403, 1st paragraph. Protein patterning in T lymphocytes (T cells) is outlined on page 400. The method is used to detect early stages of viral infection because a virus must replicate cellular components associated with the nuclear matrix. Such changes are evident in protein patterning analysis. See page 403 – 4.3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use protein patterning procedures to evaluate cancer diseases or virus cell lines (like T cells) and further allowing for cellular replication distinctions (differential development) via polyacrylamide as taught by Cupo in the high through put protein pattering procedure of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) because Cupo taught that two-dimensional gels can determine tissue-type specific differences in nuclear matrix proteins and the differences between normal and carcinogenic cells. See page 402 - 4.2 Further these proteins play an important role in cells. Utilization of the proteins can lead to the development of diagnostic agents to detect various diseased conditions of the cell and organism (including cancer and viruses). Cupo page 404.

III. Claims 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) and in further view Spencer et al. (WO 93/12248).

Please see Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) as set forth above.

Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) differ from the instant invention in not specifically teaching cell lysate comparison procedures wherein the cell population is modified. In particular, the comparison of cells from two different disorders.

However Spencer et al. disclose the evaluation of binding patterns to identify cell lysates involved in inflammatory conditions. The cell population is modified to test for binding capabilities. See abstract and page 2 line 34 –page 3 line 1. Cell lysates or cell lines labeled for detection are exemplified on page 6 line 36 to page 7 line 13. Page 9 lines 8-22 describe various cell comparisons as recited in the claims. See activated T cell/stimulated (page 9 line 12), fetal cell/developmental stage (page 9 line 20), tonsil and spleen cells/different tissue types (page 14 line 34), resting state (page 14 line 39), mouse-cell line (page 23), human-cell lines (page 19-20). The use of these binding analyses, were taught to be useful in the diagnosis and treatment of inflammatory diseases, such as Crohn's disease.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use various cell lysate comparisons as taught by Spencer et al. in the method of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) because Spencer et al. taught that the use of these binding analyses, were taught to be useful in the diagnosis and treatment of inflammatory diseases, such as Crohn's disease. See abstract.

Response to Arguments

Applicant's argument's filed 4/6/06 against the previously cited art is MOOT because new claims and rejections have been presented in the instant office action.

7. For reasons aforementioned, no claims are allowed.

Remarks

8. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Fields et al. (U.S. Patent #5,283,173) disclosed systems to measure protein-protein interactions.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Remsen 3C-59
(571) 272-0816
10/16/06

LONG V. LE 10/16/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600